

**PATENT COOPERATION TREATY
PCT**

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 510140/EJH/ar	<div style="display: flex; justify-content: space-between;"><div>FOR FURTHER ACTION</div><div>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</div></div>
International application No. PCT/AU2004/001440	<div style="display: flex; justify-content: space-between;"><div>International filing date (day/month/year) 20 October 2004</div><div>(Earliest) Priority Date (day/month/year) 21 October 2003</div></div>
Applicant MELBOURNE HEALTH et al	

An international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of **5** sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

☒ Certain claims were found unsearchable (See Box No. II).

☐ Unity of invention is lacking (See Box No. III).

With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

HBV variants detection and application

With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☒ none of the figures is to be published with the abstract.

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No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

International search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

☒ Claims Nos.: 19, 45, 56, 67, 78, 93, 105 and 117 in part
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claims 19, 45, 56, 67, 78, 93, 105 and 117 are not clear, the claims refer to a number of mutations in the HBV DNA polymerase and one of them is rt180L. It is not clear what amino acid is mutated to L at position 180 of the reverse transcriptase part of the polymerase. As such, no comment is made on the novelty and inventive step of these claims, in so far as they relate to rt180L.

☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

International Searching Authority found multiple inventions in this international application, as follows:

- ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
- ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
- ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

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CLASSIFICATION OF SUBJECT MATTER

Cl. 7: C12N 7/00, C07K 14/02, C12Q 1/70

According to International Patent Classification (IPC) or to both national classification and IPC

FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PIDS, CA, MEDLINE (HEPATITIS B, HBV, VARIANT, RESISTANT, MUTANT, NUCLEOSIDE ANALOG, C, ADV, LMV, TFV, POLYMERASE, RESIST)

DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2003/087351 A1 (MELBOURNE HEALTH) Published 23 October 2003. (Whole document)	1-18, 21, 22, 27-44, 47, 48, 53-55, 58, 59, 64-66, 69, 70, 75-77, 80, 81, 88-92, 95, 96, 101-104, 107, 108, 113-116, 119, 120 and 125-130

☒ Further documents are listed in the continuation of Box C☒ See patent family annex

* Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
* document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
December 2004

Date of mailing of the international search report

20 DEC 2004

Name and mailing address of the ISA/AU

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INTERNATIONAL SEARCH REPORT

International application No.

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(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2003/066841 A1 (MELBOURNE HEALTH) Published 14 August 2003. (Whole document)	1, 3, 17, 18, 21, 22, 25-27, 29, 43, 44, 47, 48, 51-55, 58, 59, 62-66, 69, 70, 73-77, 80- 83, 86-92, 95, 96, 99-104, 107, 108, 111, 112, and 125- 130
PX	WO 2004/031224 A2 (GILEAD SCIENCES, INC.) Published 15 April 2004 (Page 2, line 22; Page 3, lines 4-11; Page 5 lines 20-23; Claims 1-3, 18, 19)	1-3, 17, 18, 21, 27-29, 43, 44 and 47
X	WO 2000/061758 A1 (NORTH WESTERN HEALTH CARE NETWORK) Published 19 October 2000 (Page 19, line 28; Pages 33, line 33- page 35, Claims 31-33)	1, 3, 101, 104, 106, 108 and 112
X	Torresi, J., et al; "Restoration of Replication Phenotype of Lamivudine-Resistant Hepatitis B Virus Mutants by Compensatory Changes in the "Fingers" Subdomain of the Viral Polymerase Selected as a Consequence of Mutations in the Overlapping S Gene". Virology (2002); Vol 299: 88-99. (Abstract; Page 89, col 1; Page 93, discussion to page 94, col 1, para 1)	1, 3, 21, 113 and 114
X	Ono, S. K., et al; "The polymerase L528M mutation cooperates with nucleotide binding-site mutations, increasing hepatitis B virus replication and drug resistance". Journal of Clinical Investigation (2001); Vol 107(4): 449-455. (Abstract; Page 449; Page 451, col 1, para 1; Page 452 col 2 last line to page 453, col 1, lines 1-5)	1, 3, 17, 21, 75, 76, 80 and 82

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

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is Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member	
VO	03087351	None	
VO	03066841	CA	2475446 EP 1476543
VO	04031224	None	
VO	0061758	AU	36480/00 EP 1169452

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX